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(54) Method for manufacturing an extrusion profile with variable properties along its length and catheters made in accordance with this method.

(57) Method for manufacturing an extrusion profile comprising simultaneously conveying a number of, in the circumferential direction of the profile distributed streams of material of at least two different compositions to a moulding-nozzle (2) and of making these streams flow together in the moulding-nozzle (2). At least one of the streams is turned on and/or off in a controlled manner and the combined stream of materials is allowed to cool off to form an extrusion profile (3). The catheter is a tube-like extrusion profile, containing at least one section the wall of which comprises bands of material of different composition, extending in lengthwise direction.

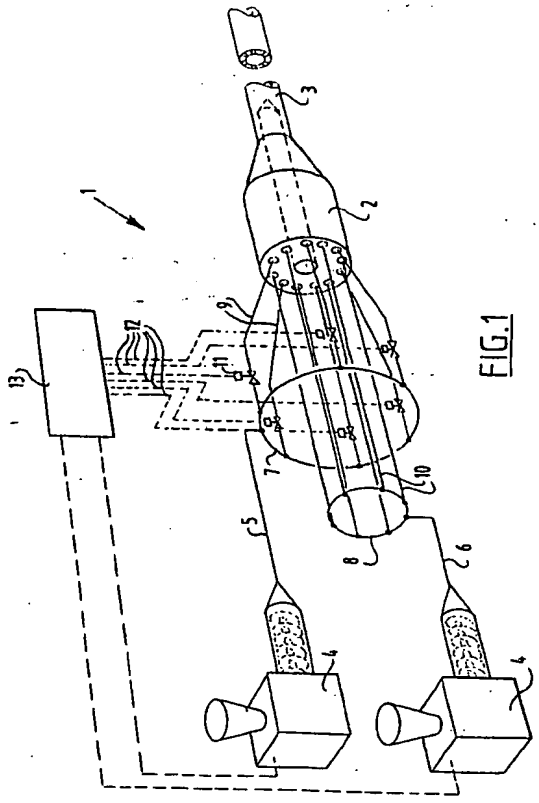

FIG.1

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The invention relates to a method for making an extrusion profile with variable properties along its length, such as varying degrees of stiffness.

Such a process for making a catheter is known. Employing this familiar method, different streams of material are turned on during the extrusion process, so that the extrusion profile is longitudinally made up of sections of varying composition.

The object of the invention is to improve a method of the type as described in the preamble.

According to the invention this can be achieved with the measure as characterised in claim 1. The extrusion profile manufactured in accordance with the method according to the invention in cross section has areas of materials of different composition. Along the length of the profile the overall surface area of each of the different types of material may vary and consequently the properties of the extrusion profile will vary.

A simple and effective embodiment of the process is achieved with the measure as set out in claim 2.

The process of the invention together with the preferred measure as set out in claim 3 is especially useful for the manufacture of catheters such as catheters used for angiographic purposes. Such catheters should be pliable, ie of limited stiffness at the distal end in order to easily follow the course of a blood vessel. More towards the proximal end such a catheter is preferably stiffer in order to convey the pressure, exerted on the catheter on insertion, to its distal end.

A material which displays a greater stiffness than the other materials used could for instance be a solid material such as a fibre bundle. A fibre bundle can easily be incorporated in the extrusion profile during the extrusion process. One could start the extrusion off with for example the maximum number of streams of solid material in the form of fibre bundles whereby, during the course of the extrusion process, these are cut off gradually so that an extrusion profile is formed which is initially stiff comparatively speaking but more pliable towards the end.

Another embodiment of the method of the invention is characterised in claim 5. The advantage of using streams of molten material is that it is not only easy to turn certain streams off but just as easy to turn these on. In the case of a stream of solid material this is more difficult to achieve. By only using streams of molten material it is possible to produce within one length of extrusion profile a number of sections of which the properties alter in the same manner.

The invention relates to and also provides catheters manufactured by a method in accordance with the invention. These catheters ar characterised in that at least partly the wall consists of longitudinal bands of material of different composition.

In order to obtain a desired development of properties in a longitudinal direction the measure as set out in claim 7 is preferably employed. When one wants to vary the stiffness, the cross-section of each band containing the stiffer material can for instance be reduced longitudinally while the cross-section of an adjoining band containing less stiff material increases correspondingly.

In stead of causing the total cross-section of the different bands of material to vary while keeping the number of bands constant, one could also vary the number of bands. In the case of a catheter manufactured in accordance with the method of the invention the number of bands made up of a stiffer material could be reduced gradually towards the distal end of the catheter.

The invention will be explained in greater detail in the following description with reference to the attached drawings.

Fig. 1 shows schematically the manufacturing method of the invention.

Fig. 2 shows an extrusion profile manufactured by the method of the invention.

Fig. 3 shows a cross-section at III-III in fig. 2.

Fig. 4 shows a cross-section at IV-IV in fig. 2.

Fig. 5 and **6** show two other extrusion profiles manufactured by the method of the invention.

Fig. 1 shows schematically an extrusion device which can be used to carry out the method of the invention. This device 1 comprises a moulding-nozzle 2 in which the extrusion profile 3 is formed. The embodiment of the method as described here, involves the use of streams of material of two different compositions. Each of the materials is placed in an extruder 4 in the for extrusion required correct degree of liquidity and at the right pressure. The material coming from the first extruder 4 is conveyed, through line 5, to a distribution line 7. From this distribution line a number of lines 9 branch off, each of which can convey a stream of material.

The second extruder 4 leads to a line 6, also connected to a distribution line 8 which, in its turn links up with a number of lines 10 conveying separate streams of material.

As fig. 1 shows there are in this embodiment twelve, in the circumferential direction of the tube-like profile 3 distributed streams of material of two different compositions.

The different materials can be incorporated in a pattern of alternate bands in the wall of profile 3.

In each of the lines 9, conveying the streams of material of the first composition, cut-off valves 11 have been arranged. Each of these cut-off valves 11, can be controlled by means of control lines 12 by a control means 13. The control means 13 can open or close the cut-off valves 11 during the extrusion process in a controlled manner and consequently the streams of material conveyed through the corresponding lines 9 can be turned on and off in a similar controlled manner. The control means 13 can be

made to control the extruders 4 as well. The opening and closing of the cut-off valves 11 is preferably programmed in a preset cycle. Manual operation is obviously possible as well.

The streams of material conveyed through the lines 9 and 10 flow together in the moulding-nozzle 2. After allowing the combined stream of materials to cool off in the usual manner, the extrusion profile 3 has been formed.

In the embodiment as shown in fig.I the streams of material through the lines 10 are conveyed continuously and those through the lines 9 can be turned on and off in a controlled manner by the cut-off valves 11.

When the control means 13 closes all cut-off valves 11, the extrusion profile 3 will be made entirely of material conveyed through the lines 10. When a cut-off valve 11 is opened the extrusion profile 3 will contain a longitudinal band made of material coming from the first extruder 4, while the remainder of the cross-section of the profile 3 will be made of material coming from the second extruder 4.

This situation is shown in fig. 3, representing a cross-section at III-III in fig. 2. It can be seen that in the annular cross-section of the catheter 3 there is one band 16 made of material from the first extruder, while the rest of the cross-section consists of material 15 from the second extruder.

When all cut-off valves 11 have been opened, the profile will have a cross-section as shown in fig. 4, in which case material 15 and material 16 alternate in a regular fashion in circumferential direction.

By opening and closing the cut-off valves 11 in a controlled manner the extrusion profile will display varying properties in a linear direction corresponding to the properties of the constituent streams of material. When for instance the material from the first extruder 4 is stiffer when cooled off than the material from the second extruder, the extrusion profile 3 with a cross-section as shown in fig. 3 will be less stiff than a section of the extrusion profile with a cross-section as shown in fig. 4. By varying the number of cut-off valves 11 as desired, the stiffness of the extrusion profile can be made to alter gradually in a linear direction.

Turning the streams of material on and off can be done either abruptly or gradually. When it is done gradually the cross-section of the band made of the stream of material concerned in the extrusion profile will vary accordingly and thus there will be a more gradual transition of the properties of the material.

The section of extrusion profile 19 as shown in fig.5 forms the basic material for a catheter. It is made up of mat rials of two different compositions. The material of the first composition is, when cooled off, stiffer than that of the second composition. In the first section 20, six bands of the first material have been incorporated in between six bands of the second material. This section 20 is therefore stiff comparatively speaking. The second section 21 constitutes a transitional section and contains two bands of the stiff material while the remainder is made up of the less stiff material. During the extrusion process in this example, four streams of the material of the first composition were turned off at the point of transition from the first section to the second section 21. At the point of transition from the second section 21 to the third section 22 of the material, one of the two remaining streams of material of the first composition was turned off, so that the third section 22 contains only one band of the stiffer material. Consequently the end-section 22 is considerably more pliable than the first section 20. In addition to a property such as the compliance of the material also other properties can be incorporated in the extrusion profile. The basic material 24 for a catheter for instance, comprises a first section 25 made of a material of a first composition while in the second section a band 27 of a different material has been included. Because of this one band 27 the compliance properties of the basic material have been altered. When the basic material 27 has a high tensile stiffness and is made of a fibre bundle for instance, the profile will bend in a particular preferential direction when a longitudinal compressive force is exerted on the end.

Although the above description refers continually to streams of material of two different compositions whereby the streams with a certain composition can be turned on and off at will, the invention is not limited to this. Streams of material with more than two different compositions can be combined and turning the streams of material on and off is not limited to streams of the same composition.

Claims

1. Method for manufacturing a tube-like extursion profile with an annular cross-section, comprising simultaneously conveying a number of, in the circumferential direction of the profile divided streams of material of at least two different compositions to a moulding-nozzle, wherein the streams of material of the same composition, are supplied alternating with those of another composition, distributed evenly in the circumferential direction, making these streams flow together in the moulding-nozzle whereby at least one of the streams can be turned on and/or off in a controlled manner during the extrusion method and allowing the combined stream of materials to cool off into an extrusion profile.

2. Method according to claim 1, wherein the streams which are turned on and/or off in a controlled manner are streams of material of the

same composition.

3. Method according to claim 2, wherein the compositions of the materials differ in such way that the stiffness of those materials is different in the cooled off state.

4. Method according to claim 3, wherein at least one of the streams is a stream of solid material such as a fibre bundle.

5. Method according to any of the claims 1 to 3, wherein all streams are streams of molten material.

6. Catheter with a tube-like extrusion profile manufactured by the method according to any of the preceding claims containing at least one section the wall of which consists of longitudinal bands of material of different composition.

7. Catheter as claimed in claim 6, wherein the cross-section of at least two adjoining bands varies inversely in longitudinal direction.

8. Catheter as claimed in claim 7, wherein the bands comprise materials of different stiffness and wherein the total cross-section of the bands made of the stiffer material is smaller in the distal end-section of the catheter than in the remaining part.

9. Catheter as claimed in claim 8, wherein the cross-section and/or the number of bands made of the stiffer material decreases from the proximal to the distal end.

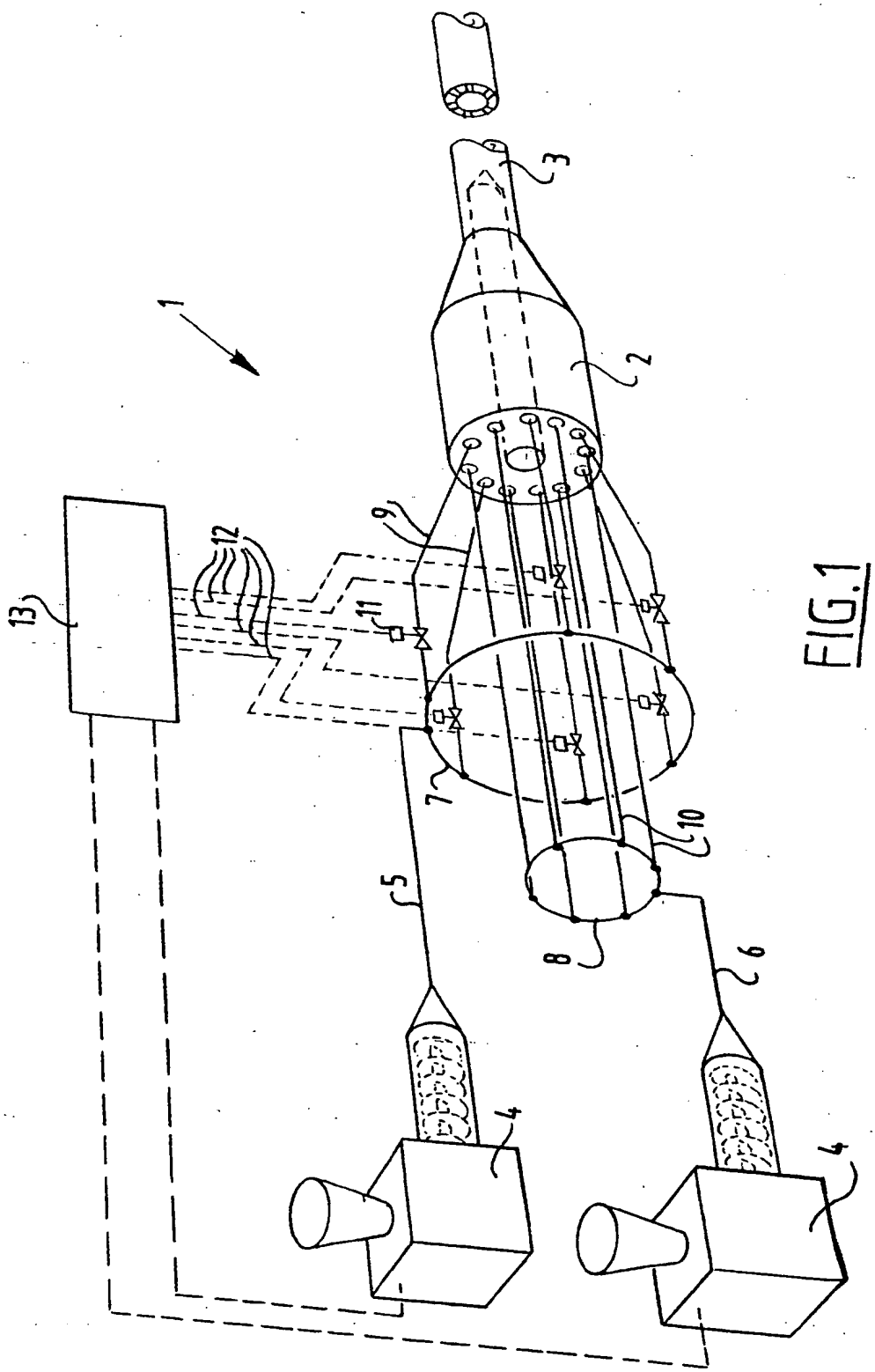
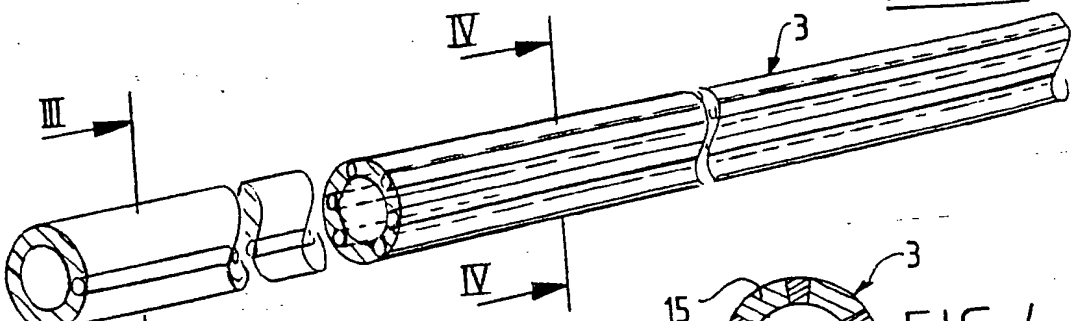


FIG.1

FIG.2



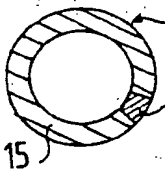


FIG.3

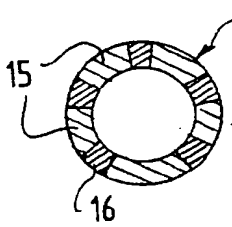


FIG.4

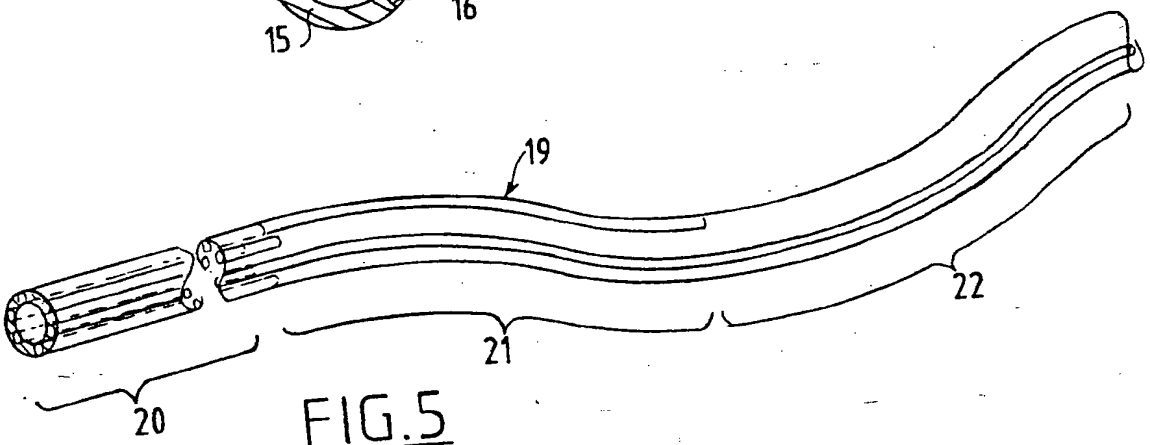


FIG.5

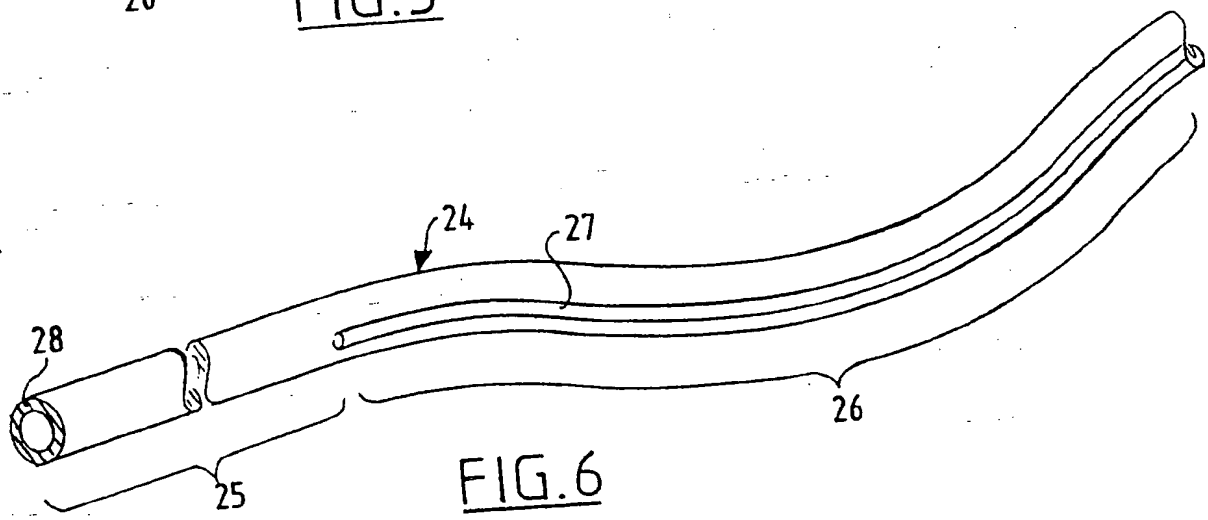


FIG.6

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EUROPEAN SEARCH REPORT

Application Number
EP 94 20 0875

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	US-A-4 276 250 (F.E. SATCHELL ET AL.) * column 1, line 16 - line 24 * * column 4, line 22 - line 26; figure 1 * * column 4, line 49 - line 56 *	1-9	B29C47/04 A61M25/00
A	EP-A-0 448 886 (BECTON DICKINSON) * page 3, line 26 - line 29; figures 1-3 *	6-9	
A	GB-A-2 191 145 (EXCELL CORP.) * page 3, right column, line 116 - line 121; figure 5 *	1,2	
A	US-A-3 752 617 (N.W. BURLIS ET AL.) * column 4, line 12 - line 59; figures 1,2,9 * * column 5, line 50 - column 6, line 3; figure 8 *	1-6,8,9	
A	DE-A-40 32 869 (H.-H. GERCKE) * column 3, line 50 - line 60; figures *	6,8,9	
A	US-A-4 182 582 (A. YOUVAL ET AL.) * column 4, line 10 - line 18; figure 2A * * figure 3 *	7	TECHNICAL FIELDS SEARCHED (Int.Cl.5) B29C A61M
A	US-A-3 825 036 (V.D. STENT) * column 3, line 15 - line 28; figure 7 *	1	
A	EP-A-0 385 942 (SOPLAR SA) * column 3, line 12 - line 23; figures 3,4 *	1	
A	EP-A-0 369 383 (CORDIS CORP.) * column 3, line 38 - line 44 *	4	
A	US-A-4 874 305 (P.E. MCGILL ET AL.) * column 2, line 44 - line 65; figures 1,2 *	1	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	31 May 1994	Topalidis, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
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E : earlier patent document, but published on, or after the filing date
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